

SEP - 4 2001

K012468

**510(k) Summary  
For N/T Protein Control SL**

**1. Manufacture's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Marburg GmbH  
Emil-von-Behring Str. 76  
Marburg/Germany

Contact Information: Dade Behring Inc.  
Glasgow Site  
P.O. Box 6101  
Newark, Delaware 19714  
Attn: Rebecca S. Ayash  
Tel: 302-631-6276

Preparation date: July 31, 2001

**2. Device Name/ Classification:**

N/T Protein Control SL: Quality Control Material (assayed)

Classification Number: Class I (862.1660)

**3. Identification of the Legally Marketed Device:**

N/T Protein Control SL (K002852)

**4. Device Description:**

N/T Protein Control SL is a liquid control prepared from human serum with stabilizers and preservative. It is intended to be used as an accuracy and precision control for the determination of human serum proteins by immunonephelometry with BN™ Systems and by immunoturbidimetry with the TurbiTimeSystem.

**5. Device Intended Use:**

N/T Protein Controls SL/L, M, and H are for use as accuracy and precision assayed controls in the determination of the following human serum proteins by immunonephelometry with BN™ Systems: IgG, IgG<sub>1-4</sub>, IgA, IgM, C3c, C4, Transferrin, Albumin,  $\alpha_1$ -antitrypsin,  $\alpha_2$ -macroglobulin, Haptoglobin,  $\alpha_1$ -acid glycoprotein, Prealbumin, Hemopexin, Ceruloplasmin, RbP, Ig/L-chain lambda & kappa,  $\beta_2$ -microglobulin, soluble Transferrin Receptor (sTfR), Ferritin, IgE, and Total protein; and by immunoturbidimetry with the TurbiTimeSystem: IgG, IgA, IgM, C3c, C4, Transferrin, Albumin, Haptoglobin,  $\alpha_1$ -acid glycoprotein.

**CONFIDENTIAL**

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**6. Medical device to which equivalence is claimed and comparison information:**

The modified N/T Protein Control SL is substantially equivalent in intended use to N/T Protein Control SL (K002852) currently marketed. The modified N/T Control SL, like the current N/T Protein Control SL is intended to be used as quality control material to monitor the accuracy and precision of human serum protein assays on BN™ Systems and the TurbiTimeSystem.

**7. Device Performance Characteristics:**

**Stability:**

Stability was evaluated according to Dade Behring protocols and the control was found to be stable for at least 24 months at +2° to +8° C, as originally packaged and for at least 14 days at +2° to +8° C, once opened.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP - 4 2001

Ms. Rebecca S. Ayash  
Director, Regulatory Affairs  
Dade Behring, Inc.  
Glasgow Site, PO Box 6101  
Newark, DE 19714

Re: K012468  
Trade/Device Name: N/T Protein Control SL  
Regulation Number: 21 CFR 862.1660  
Regulatory Class: I, reserved  
Product Code: JJY  
Dated: July 31, 2001  
Received: August 2, 2001

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

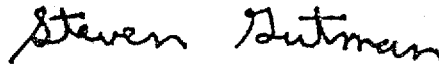
A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

**Device Name:** N/T Protein Control SL

### Indications for Use:

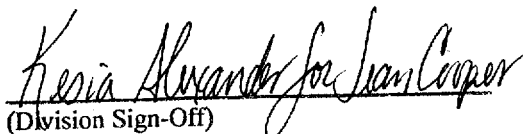
N/T Protein Controls SL/L, M, and H are for use as accuracy and precision assayed controls in the determination of the following human serum proteins by immunonephelometry with BN™ Systems: IgG, IgG<sub>1-4</sub>, IgA, IgM, C3c, C4, Transferrin, Albumin,  $\alpha_1$ -antitrypsin,  $\alpha_2$ -macroglobulin, Haptoglobin,  $\alpha_1$ -acid glycoprotein, Prealbumin, Hemopexin, Ceruloplasmin, RbP, Ig/L-chain lambda & kappa,  $\beta_2$ -microglobulin, soluble Transferrin Receptor (sTfR), Ferritin, IgE, and Total protein; and by immunoturbidimetry with the TurbiTimeSystem: IgG, IgA, IgM, C3c, C4, Transferrin, Albumin, Haptoglobin,  $\alpha_1$ -acid glycoprotein.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K012468

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